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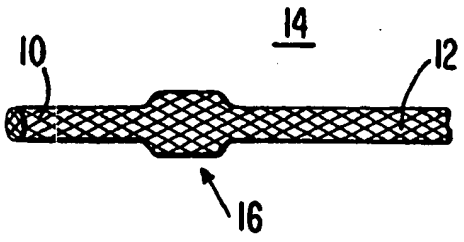
(54) Title: ARTIFICIAL TUBULAR BODY ORGAN GRAFTS

(57) Abstract

Artificial tubular grafts have a tubular framework of a first highly elastic material (e.g., a mesh of nitinol) covered by a substantially continuous web of a second highly elastic material (e.g., silicone). Prior to application of the second material, the framework is handled so that it will permit the finished and installed graft to readily respond to natural pressure pulses in blood flowing through the graft by elastically circumferentially expanding. The resulting pulsation of the graft is a strong deterrent to the formation of undesirable blood clots on the inner wall surface of the graft.



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ARTIFICIAL TUBULAR BODY ORGAN GRAFTS

Background of the Invention

This invention relates to artificial, tubular, body organ grafts, and more particularly to improving the bio-utility of such grafts.

Tubular grafts for inclusion in a patient's circulatory system are known. However, a problem with many such grafts is that they tend to become occluded by blood clots. One possible explanation for such clotting in artificial grafts may be that the grafts are too circumferentially rigid. Unlike natural blood vessels, which tend circumferentially expand and contract in response to the natural pressure pulses in the blood flowing through them, artificial grafts tend to be less responsive to such pressure pulses. The resulting relatively static walls of the graft provide surfaces on which clotting can build up undisturbed until the graft is occluded, thereby defeating the purpose for which the graft was installed.

In view of the foregoing, it is an object of this invention to provided improved artificial grafts.

It is a more particular object of this invention to provide artificial, tubular, grafts that

circumferentially pulsate in response to pressure pulses in blood flowing through them.

It is another object of this invention to provide methods for making artificial, tubular, grafts that promote circumferential pulsation of the finished and installed graft in response to pressure pulses in blood flowing through the graft.

Summary of the Invention

These and other objects of the invention are accomplished in accordance with the principles of the invention by forming a framework for the graft of a first highly elastic material such as a mesh of nitinol. The framework is initially produced with a tube circumference or peripheral dimension somewhat larger than the desired nominal circumference or peripheral dimension of the finished graft. The framework is then either set in its initial circumference, or its circumference is first somewhat reduced and then the framework is set. Setting of the framework establishes the size and shape to which the framework will tend to return when it is not subject to externally applied stress (i.e., the so-called neutral state of the framework). For example, setting may be produced by heating the framework to anneal it. After the framework has been set, if its circumference was not reduced prior to setting, the circumference of the framework is now reduced and the framework is coated with a substantially continuous web of a second highly elastic material such as silicone. Alternatively, if the framework was reduced in circumference prior to setting, then the framework can be coated with such a web without substantial further circumference

modification. After the web of the second material has been applied, the material of that web is cured to produce a finished graft.

With either variation of the graft production process, there is sufficient framework material present in the finished and installed graft to allow it to readily elastically deform to or at least toward its initially relatively large circumference (a so-called expanded state of the graft) in response to pressure pulses in the blood flowing through the graft. In the variation in which the framework is set before being reduced in circumference, the web of the second elastic material tends to hold the framework in its reduced circumference (the nominal circumference of the graft). However, the web easily elastically deforms to allow the circumference of the graft to increase in pulsatory fashion in response to pressure pulses in the blood flowing through the graft. Note that in producing this pulsatory circumferential expansion, the blood pressure pulses are aided by the prestress which remains in the framework. In the variation in which the framework is reduced in circumference prior to being set, there is no prestress in the framework of the finished graft. Nevertheless, as stated earlier, there is sufficient material in the framework to allow it to readily circumferentially pulsate in response to pressure pulses in the blood flow in the graft.

The above-described pulsatory circumferential variation of the grafts of this invention greatly reduces the tendency of clots to form on inner surfaces of these grafts.

Further features of the invention, its nature and various advantages will be more apparent from the

accompanying drawings and the following detailed description of the preferred embodiments.

Brief Description of the Drawings

FIG. 1 is a simplified, substantially elevational view of an illustrative embodiment of a first component of a graft in accordance with this invention at a first point in an illustrative process for making a graft in accordance with the invention.

FIG. 2 is a view generally similar to FIG. 1 showing a later stage in the illustrative process which includes FIG. 1.

FIG. 3a is a view generally similar to FIG. 2 showing a still later stage in the illustrative process which includes FIG. 2.

FIG. 3b is a view generally similar to FIG. 3a showing an alternative to FIG. 3a.

FIG. 4 is a view generally similar to FIG. 3a or 3b showing a finished graft installed and in use, and illustrating in simplified and exaggerated form some of the behavioral characteristics of the graft in accordance with this invention.

FIG. 5 is another view similar to FIG. 1 showing an early stage in another illustrative process for making grafts in accordance with this invention.

FIG. 6 is a view generally similar to FIG. 5 showing a later stage in the illustrative process which includes FIG. 5.

FIG. 7 is a view generally similar to FIG. 6 showing a still later stage in the illustrative process which includes FIG. 6.

Detailed Description of the Preferred Embodiments

A first illustrative embodiment of the invention is depicted in FIGS. 1-4. In FIG. 1 a tubular framework 10 of a first highly elastic material is formed. For example, framework 10 may be an open mesh made of nitinol. A presently particularly preferred way of making such a mesh is to braid strands of nitinol wire around a rod or tube having the approximate circumference desired for framework 10. For example, strands of 0.002 inch diameter nitinol wire may be braided around a 10 mm diameter rod or tube. These dimensions are only illustrative and other dimensions may be used if desired. Similarly, although braiding is a presently preferred way of producing tubular framework 10, it will be understood that there are many alternatives to braiding, such as weaving, knitting, felting, perforating an initially continuous tube, etc.

The next step is illustrated by FIG. 2, which shows the tubular framework 10 from FIG. 1 being set so that it becomes a free-standing structure with a memory for its depicted size and shape. Any suitable technique may be used for setting framework 10. For example, if framework 10 is made of nitinol, the framework may be treated with heat to anneal it. Other setting techniques may be used for other framework materials. For example, controlled exposure to suitable liquid or vapor solvents may be used to set frameworks 10 of polymeric materials.

In FIG. 3a or 3b the free-standing framework 10 from FIG. 2 is elastically somewhat reduced in diameter. FIG. 3a illustrates doing this by stretching the framework axially. This is preferably done with a

mandrel 20 of approximately the desired reduced diameter inside the framework so that the framework reduces uniformly to the desired diameter. FIG. 3b illustrates an alternative in which the framework 10 from FIG. 2 is elastically reduced in diameter by inserting it into a tube 30, the inner diameter of which is the desired reduced outer diameter of framework 10. In the example in which the diameter of framework 10 in FIGS. 1 and 2 is 10 mm, the reduced diameter of the framework in FIG. 3a or 3b may be about 8 mm. Thus the outer diameter of the mandrel 20 around which framework 10 is stretched in FIG. 3a would be approximately 8 mm in this example, or the inner diameter of tube 30 in FIG. 3b would again be approximately 8 mm in this example.

While framework 10 is in the condition shown in FIG. 3a or 3b, the framework is coated with a substantially continuous covering web 12 of a second highly elastic material. A particularly preferred material for web 12 is silicone, but other suitable materials may be used if desired. The web material may be applied as a liquid and then cured to a highly elastic solid membrane. Framework 10 is preferably embedded in the material of the web, and the web spans all the interstices in the framework to produce a substantially continuous tube. The outer surface of mandrel 20 in FIG. 3a or the inner surface of tube 30 in FIG. 3b helps the web form on the framework with the above-described characteristics.

After the material of web 12 has cured, the resulting finished graft 14 is removed from mandrel 20 or from tube 30. Web 12 tends to maintain the diameter of framework 10 and therefore graft 14 at what it was on mandrel 20 or in tube 30. Thus the nominal diameter

of graft 14 is somewhat less than the diameter of framework 10 in FIGS. 1 and 2. Nevertheless, framework 10 is trying to return to its larger, FIG. 2 diameter. Thus framework 10 is somewhat prestressed by web 12 in graft 14. When graft 14 is installed in a patient's circulatory system so that blood can flow through it, and when even a relatively small, natural, blood pressure pulse is added to the prestress in framework 10, graft 14 readily responds to the blood pressure pulse by elastically increasing in circumferential size. For example, graft 14 may easily pulsatorily expand to the original diameter of framework 10 in FIG. 2. Such a pulsatory bulge is shown at 16 in graft 14 in FIG. 4. Bulge 16 may move axially along graft 14 with a pressure pulse propagating through the blood in the graft. Such pulsation of the walls of graft 14 is extremely effective in discouraging the formation and retention of clots on the inner wall surface. In this way graft 14 better mimics the behavior of natural blood vessels.

An alternative illustrative embodiment of the invention is shown in FIGS. 5-7, with the end result again being as shown in FIG. 4.

FIG. 5 is similar to FIG. 1. Again, tubular framework 10 is formed with a diameter larger than the desired nominal diameter of the finished tubular graft 14. For example, if the desired nominal diameter of the finished graft is 5 mm, framework 10 may be formed with a diameter of approximately 10 mm in FIG. 5.

In FIG. 6 framework 10 is reduced in diameter by stretching it axially over a mandrel 20 which has a smaller diameter than the diameter of framework 10 in FIG. 1. For example, the diameter of mandrel 20 may be approximately the desired nominal diameter of finished

graft 14 (e.g., 5 mm in the specific example mentioned in the preceding paragraph). With framework 10 in the condition shown in FIG. 6, the framework is set as described above in connection with FIG. 2. As a result of being thus set, framework 10 becomes a free-standing structure which tries to maintain the shape and size shown in FIG. 6.

In FIG. 7 the set framework 10 from FIG. 6 is covered with a web 12 of a second highly elastic material as described above in connection with FIG. 3a. As a further alternative, the framework 10 from FIG. 6 could be put inside a tube like tube 30 in FIG. 3b for covering with web 12 as described above in connection with FIG. 3b. After the web material has been applied, it is cured to produce a finished graft 14 as shown in FIG. 4. When produced as described above in connection with FIGS. 5-7, graft 14 again behaves substantially as has been described in connection with FIG. 4. The graft 14 that is made as shown in FIGS. 5-7 does not have the prestressed framework 10 described above in connection with FIGS. 1-3, but there is enough framework material present in the structure so that it can readily elastically increase in diameter as shown locally at 16 in FIG. 4 in response to a pressure pulse propagating along the blood flowing through the graft. A graft 14 made as per FIGS. 5-7 therefore performs very similarly to a graft 14 made as per FIGS. 1-3.

It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the particular graft materials and dimensions mentioned above are only illustrative, and other materials and/or dimensions can

be used if desired. The frame material is preferably an elastic material. Preferred materials are metal, although polymeric materials may also be used. The presently most preferred material is nitinol, and the presently most preferred structure for frame 10 is a braid of nitinol wires.

The web 12 which covers the frame is preferably an elastic, rubber-like material which substantially fills the apertures in frame 10. The covering 12 may be inside the frame structure, outside the frame structure, or both inside and outside the frame structure. Preferred rubber-like materials for the covering are polymeric materials, especially polymeric rubber materials. The presently most preferred rubber-like material is silicone. Examples of other suitable rubber-like materials are stretchable urethane, stretchable PTFE, natural rubber, and the like. For some applications it may be desirable to make the covering porous. Other applications may not benefit from such porosity. Thus the covering can be made either porous or non-porous as desired.

The graft structure may include one or more coatings over the above-described covering 12. The coating(s) may be inside the graft tube, outside the graft tube, or both inside and outside the graft tube. Possible coating materials include bio-compatible materials and/or drugs. Examples include hydrophilic polymers such as hydrophilic polyurethane (to create a lubricious surface), parylene (a polymer commonly used to coat pacemakers), PTFE (which may be deposited from a PTFE vapor using a process that is sometimes called vapor transport), the drug Heparin (a common anti-coagulant), collagen, human cell seeding, etc. One purpose of such a coating may be to give the coated

surface a very high degree of bio-compatibility and/or a very high degree of smoothness. Any coatings that are used on the graft preferably do not interfere with its elasticity.

The graft structure may or not include hooks, barbs, flaps, or other similar structures for such purposes as helping to anchor the graft in the body, provide anastomoses between the graft and existing body tubing, etc. If provided, such hooks, barbs, flaps, and the like may be extensions of the frame structure or may be molded with or otherwise added to the frame or covering.

The most preferred grafts of this invention (e.g., those with a nitinol frame and silicone covering) are highly elastic. The elastic nature of these graft structures allows them to be deployed less invasively (e.g., intravascularly or at least percutaneously; see, for example, Goldsteen et al. U.S. patent application No. 08/745,618, filed November 7, 1996, which is hereby incorporated by reference herein in its entirety). This avoids or reduces the need for surgical implantation. For example, a tubular graft of this construction can be stretched to several times its relaxed length, which greatly reduces its diameter. This facilitates intravascular delivery of the graft. When released from the delivery apparatus, the graft automatically returns to its relaxed length and diameter, with no ill-effects of any kind from its previous deformation.

In the grafts of this invention that are made with a braided nitinol wire frame and a silicone covering, the preferred wire diameter is in the range from about 0.0005 to about 0.01 inches. An especially preferred wire diameter is about 0.002 inches. The

preferred silicone covering thickness is in the range from about 0.00025 to about 0.1 inches. Two covering layers may be used: one inside and one outside the frame structure. If the covering is made porous, the preferred pore size is in the range from about 1 to about 500 microns. An especially preferred pore size is about 30 microns. The preferred covering porosity is in the range from about 50% to about 95%. In other words, from about 50% to about 95% of the volume of the covering is pore space. As mentioned above, however, porosity of covering 12 is optional, and the covering can be made substantially non-porous if desired. If any coatings are applied to the graft, they are preferably thinner than the covering.

If one or more coatings are desired on the graft, the coating may be done at any suitable and convenient time. The coating or coatings may be applied using any suitable technique such as dipping, electrostatic spraying, vapor transport, in vitro cell reproduction, etc.

A preferred method in accordance with the invention for making the graft covering 12 porous is to mix particles of another material with the covering material before applying the covering material to frame 10. The particulate material is selected as one which is stable or at least relatively stable during curing of the covering on the frame, but which can then be removed from the cured covering to leave the covering with the desired porosity. For example, the particulate material may be a salt such as ammonium carbonate, which is relatively stable at temperatures substantially below about 78°C, but which vaporizes relatively rapidly at an elevated temperature (i.e., about 78°C) that is not harmful to the cured coating

material. Any other particulate material that can be removed by vaporization or solution can be used. For example, the particulate material may be removed by dissolving in water or another solvent, by exposure to air or another vaporization medium, by heat, by vacuum, or by any other suitable means.

Porosity of the covering is believed to be beneficial for circulatory system grafts. It may promote growth of a cell structure on the inside wall of the graft. And in all uses, porosity may promote better adherence of the above-mentioned coatings to the graft.

It will also be appreciated that grafts can be made in accordance with this invention with other than the straight tubular shape shown herein. For example, tubular grafts with one or more branches can be made, and/or the graft tubes of this invention may be curved if desired. The graft tubes of this invention do not have to be circular as shown herein, but can have any desired cross sectional shape such as elliptical (e.g., as a result of use of correspondingly shaped mandrels 20). It will therefore be understood that terms like "circumference" and "diameter" are used herein as convenient generic terms for peripheral and transverse dimensions, respectively, and that there is no intention to limit the referenced geometries to strictly circular shapes. As still another example of modifications within the scope of this invention, the grafts of this invention do not have to have uniform dimension along their entire lengths, but rather they can vary in size and/or shape along their lengths. Grafts having Y, T, or other shapes can be made in accordance with this invention. All portions of the grafts do not need to have the exact same properties.

For example, axial end portions of the grafts may include connector structures that have somewhat different properties than other portions of the graft.

The Invention Claimed Is

1. A method of making a tubular body organ graft comprising:

forming a tubular framework of a first elastic material, said framework being formed with a first circumference;

setting said framework;

elastically deforming said framework to reduce its circumference from said first circumference to a second circumference; and

covering said framework with a web of a second elastic material while said framework has said second circumference.

2. The method defined in claim 1 wherein said forming comprises:

braiding strands of said first elastic material.

3. The method defined in claim 1 wherein said forming comprises:

forming said framework around a forming member which has approximately said first circumference.

4. The method defined in claim 1 wherein said setting comprises:

heating said framework.

5. The method defined in claim 1 wherein said setting comprises:

annealing said framework.

6. The method defined in claim 1 wherein said elastically deforming comprises:

axially stretching said framework.

7. The method defined in claim 6 wherein said axially stretching circumferentially reduces said framework down into contact with the surface of a mandrel which has approximately said second circumference.

8. The method defined in claim 1 wherein said elastically deforming comprises:

placing said framework in a tube having approximately said second circumference as said inner circumference.

9. The method defined in claim 1 wherein said covering comprises:

applying said second elastic material to said framework in liquid form; and

curing said second elastic material to produce said web.

10. The method defined in claim 1 wherein said framework includes nitinol.

11. The method defined in claim 1 wherein said web includes silicone.

12. A method of making a tubular body organ graft comprising:

forming a tubular framework of a first elastic material, said framework being formed with a first circumference;

reducing the circumference of said framework from a first circumference to a second circumference;

setting said framework while it has said second circumference; and

covering said framework with a web of a second elastic material.

13. The method defined in claim 12 wherein said forming comprises:

braiding strands of said first elastic material.

14. The method defined in claim 12 wherein said forming comprises:

forming said framework around a forming member which has approximately said first circumference.

15. The method defined in claim 12 wherein said reducing comprises:

axially stretching said framework.

16. The method defined in claim 15 wherein said axially stretching circumferentially reduces said framework down into contact with the surface of a mandrel which has approximately said second circumference.

17. The method defined in claim 12 wherein said elastically deforming comprises:

placing said framework in a tube having approximately said second circumference as said inner circumference.

18. The method defined in claim 12 wherein said setting comprises:

heating said framework.

19. The method defined in claim 12 wherein said setting comprises:

annealing said framework.

20. The method defined in claim 12 wherein said covering comprises:

applying said second elastic material to said framework in liquid form; and

curing said second elastic material to produce said web.

21. The method defined in claim 12 wherein said framework includes nitinol.

22. The method defined in claim 12 wherein said web includes silicone.

23. An artificial, tubular, body organ graft comprising:

a tubular framework of a first elastic material formed with a first circumference and subsequently reduced in circumference; and

a tubular web of a second elastic material applied to said framework while said framework is reduced in circumference.

24. The graft defined in claim 23 wherein said framework comprises a mesh of said first elastic material.

25. The graft defined in claim 23 wherein said framework comprises a braid of strands of said first elastic material.

26. The graft defined in claim 23 wherein said framework comprises nitinol.

27. The graft defined in claim 23 wherein said framework is embedded in said web.

28. The graft defined in claim 23 wherein said web includes silicone.

29. The graft defined in claim 23 wherein said framework is set while it has said first circumference.

30. The graft defined in claim 23 wherein said framework is set while it has said second circumference.

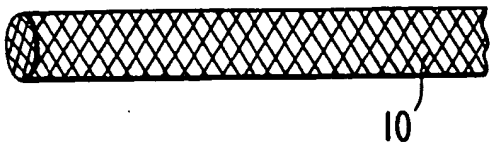

FIG.1

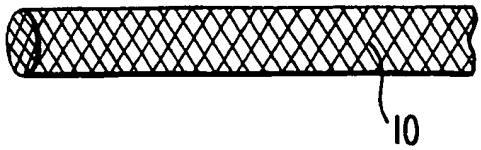

FIG.2

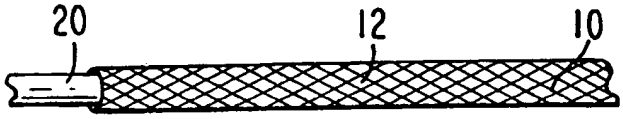

FIG.3a

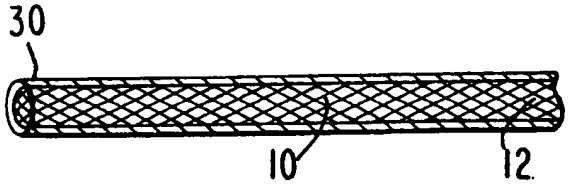

FIG.3b

FIG.4

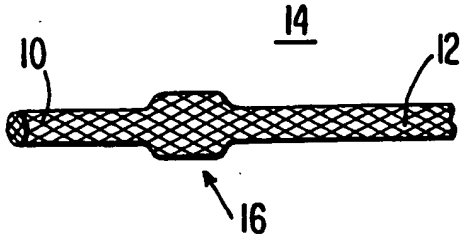

FIG.5

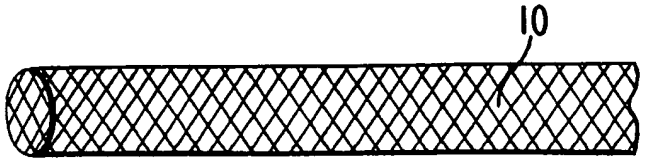

FIG.6

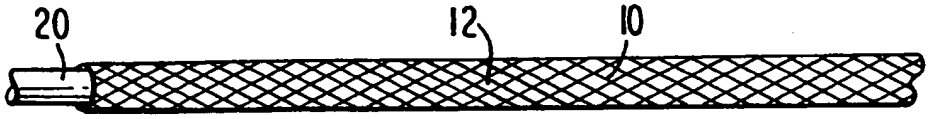

FIG.7

INTERNATIONAL SEARCH REPORT

Inte ional Application No
PCT/US 97/20061

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 12136 A (BOSTON SCIENT CORP) 9 June 1994 see page 2, line 35 - page 3, line 4; figures see page 4, line 5 - page 6, line 30 see page 18, line 26 - page 19, line 15 see page 27, line 19 - line 20 ---	1-8, 10-19, 21-30
X	WO 96 32907 A (SCHNEIDER USA INC) 24 October 1996 see page 4, line 6 - line 33; claims 2-5; figures	1,2,4,6, 9-11, 23-28
A	 --- -/--	12,13, 15,18, 20-22

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
27 March 1998	08/04/1998

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INTERNATIONAL SEARCH REPORT

Inte. ional Application No
PCT/US 97/20061

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